

**AMENDMENT OF OTHER TRANSACTION AGREEMENT (OTA)**

**OTHER TRANSACTION FOR ADVANCED RESEARCH (OTAR)**

**BETWEEN**

**JANSSEN RESEARCH & DEVELOPMENT LLC**  
920 ROUTE 202  
RARITAN, NJ 08869, USA

**AND**

**THE UNITED STATES OF AMERICA**  
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY**  
O'NEILL HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515

**CONCERNING**

**INFLUENZA PORTFOLIO AND OTHER EMERGING PATHOGENS DEVELOPMENT CANDIDATES**

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Amendment No. 0005

Effective Date of Amendment: Upon Last Signature in Section III

Other Transaction Agreement No. HHSO100201700018C

Effective Date of Agreement: August 15, 2017

Except as provided in this Amendment, all terms and conditions of the Agreement, as heretofore changed, remain unchanged and in full force and effect.

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## I. AMENDMENT PURPOSE

By the Parties' mutual agreement and within the existing Agreement's general scope, this Amendment No. 0005 bilaterally (i) (b) (4)

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ii) (b) (4)

iii) Modifies the Joint Oversight Committee (JOC) purpose to align with the restructured budget, (iv) Replaces language in Article VII (B) to clarify the calculation of the exchange rate, (v) updates the Statement of Work to reflect JOC decisions and new asset structure, (vi) updates the Recipient's Key Personnel and the Government's personnel working under the Agreement, and (vii) Other administrative updates

## II. AMENDMENTS TO AGREEMENT

A. Incorporate new budget and workplan structure to reflect two assets remaining in the portfolio.

- 1) Pursuant to Agreement Article VI(C), the budget allocation summary of assets is hereby replaced to incorporate the following.

	Invoiced					
Summary	8/15/2017 Through 12/31/2018	1/1/2019 Through 12/31/2019	1/1/2020 Through 12/31/2020	1/1/2021 Through 12/31/2021	1/1/2022 Through 12/31/2022	Total

(b) (4)

		1/1/2019	1/1/2020	1/1/2021	1/1/2022	
		through	through	through	through	Total
		12/31/2019	12/31/2020	12/31/2021	12/31/2022	
Work Package Number	Work Package Name	PERIOD 1	PERIOD 2	PERIOD 3	PERIOD 4	TOTAL

(b) (4)

(b) (4)

C. JOC Update

- 1) Agreement Article IV (B) (1) *Joint Oversight Committee (JOC)*, is deleted in its entirety and restated with the following:

The JOC will meet at critical decision points in the program, preferably face to face or alternatively by telephone conference. For agenda items strictly related to funding, a JOC will be held. The JOC will be requested to endorse the potential funding of activities which will commence upon a bona fide need being identified through programmatic, data-driven decisions for proposed work packages in the respective fiscal year the need is determined. Those funded work packages will continue until full completion. Based on some program circumstances, data and other information brought to the JOC for funding decisions may be limited. This period of performance will not be bound to fiscal years (e.g. an endorsed funded activity could last multiple years after receiving funding and commencing). Ad hoc meetings will be organized when urgent matters arise or prior to the exercising of an Option. The JOC will consist of two (2) voting members each from the Consortium and BARDA and non-voting members from the Consortium and BARDA, or other additional Consortium or U.S. Government Members (non-voting) as may be required. Additional, non-voting members may be assigned or invited by Recipient on an ad-hoc basis. Decisions to reprioritize specific projects and resources within the scope of this Agreement will be taken by consensus. In case such a decision cannot be reached in the JOC, the decision will be escalated to one BARDA and one Consortium senior management member identified at the start of the project.

## D. Exchange Rate Clarification (to be effective with the first full quarter after the mod has been signed)

- 1) Article VII (B) *Payments* language regarding exchange rates is updated to: "The Recipient will convert any foreign currency amount(s) in the invoice to U.S. dollars each

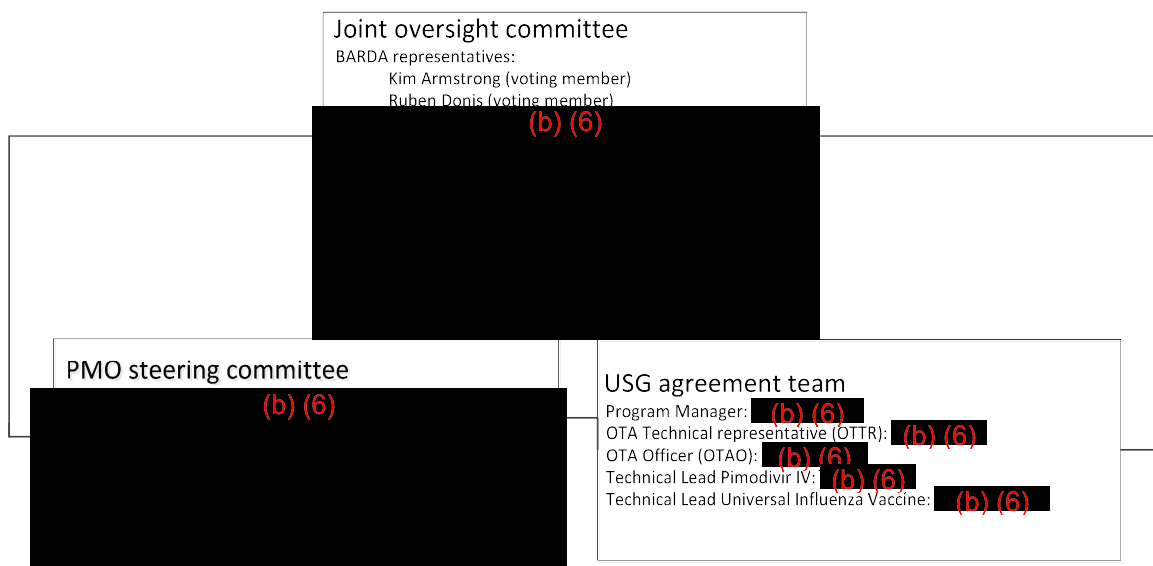
month, using the 1st of each month's foreign exchange rate index published on [www.federalreserve.gov](http://www.federalreserve.gov)"

E. Updated the Statement of Work

- 1) The Statement of Work shall be updated to reflect JOC decisions and the new asset structure. The updated SOW for incorporation in the OTA is included in Exhibit D.

F. Update of Recipient's Key Personnel and the Government's personnel working under the Agreement

- 1) Article IV *Management of the Project* Section A (3) *Organizational Chart* is deleted and replaced with the following:



- 2) Article V *Agreement Administration* is changed by revising the Paragraph entitled "Government Points of Contact" as follows:

Other Transaction Agreement Officer (OTAO/OTAS) is

(NAME) (b) (6)

(TITLE) Lead Contracting Officer & Other Transaction Agreement Officer (OTAO)

(EMAIL) (b) (6)

## G. Other Administrative Changes

- 1) Related to the budget update, Article II (A) *Term of this Agreement* is deleted in its entirety and restated with the following: "The Agreement commences on the date of the last signature hereto and continues for all work packages funded via the most recent JOC decision and modification. Further, optional work packages may be exercised in accordance with the JOC structure articulated in the amended Article IV (B) (1) *Joint Oversight Committee (JOC)* as amended by Section II C of Modification 0005 to this Agreement. The Recipient may decline "options" and such declination will be treated as a termination and Recipient shall act in accordance with the terms in Section B. The Parties may also agree mutually to extend the term of this agreement and its options by written agreement on or before the expiration of the Agreement."

Note: The current end of performance as of this modification, is April 30, 2023. This is subject to change as the agreement continues in accordance with program and JOC decisions (per the updated language above).

## III. SIGNATURES

Acknowledged, accepted, and agreed for

JANSSEN RESEARCH & DEVELOPMENT, LLC

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES  
OFFICE OF THE ASSISTANT SECRETARY FOR  
PREPAREDNESS & RESPONSE  
BIOMEDICAL ADVANCED RESEARCH & DEVELOPMENT

(b) (6)



DATE: December 19, 2019

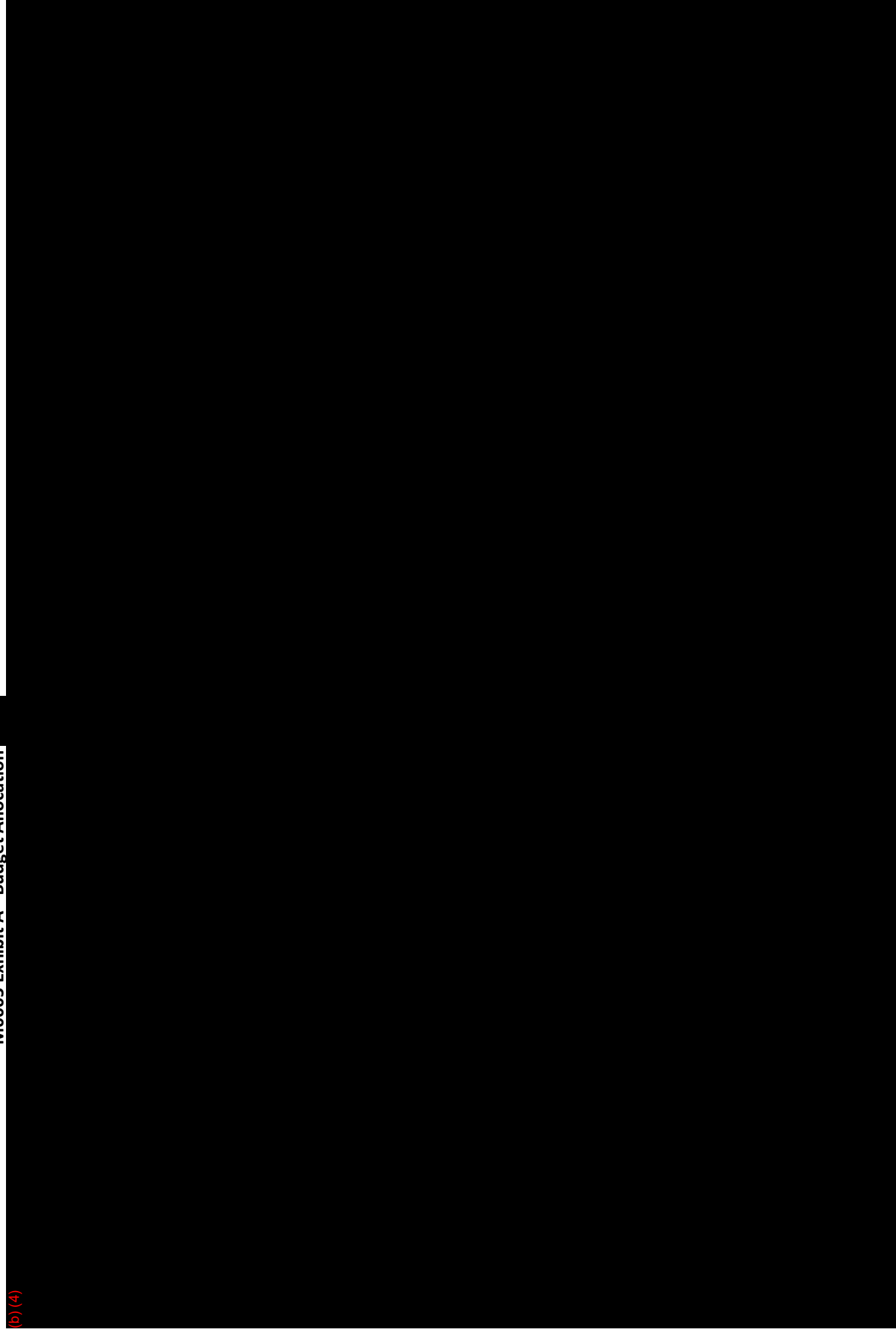
(b) (6)



DATE: DECEMBER 19, 2019

M0005 Exhibit A - Budget Allocation (b) (4)

(b) (4)



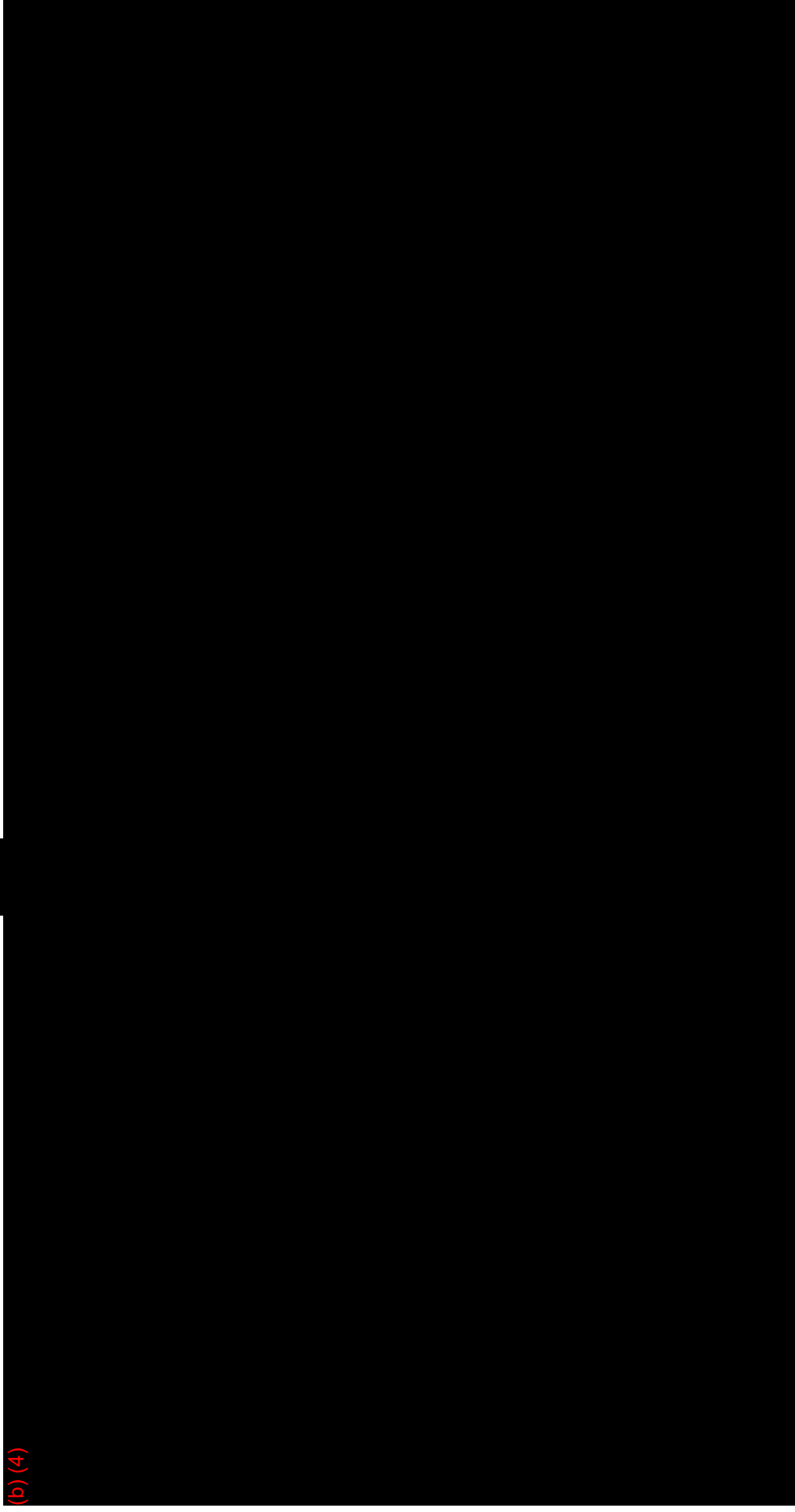




M0005 Exhibit A - Budget

(b) (4)

(b) (4)



**M0005 Exhibit A - Budget**

(b) (4)

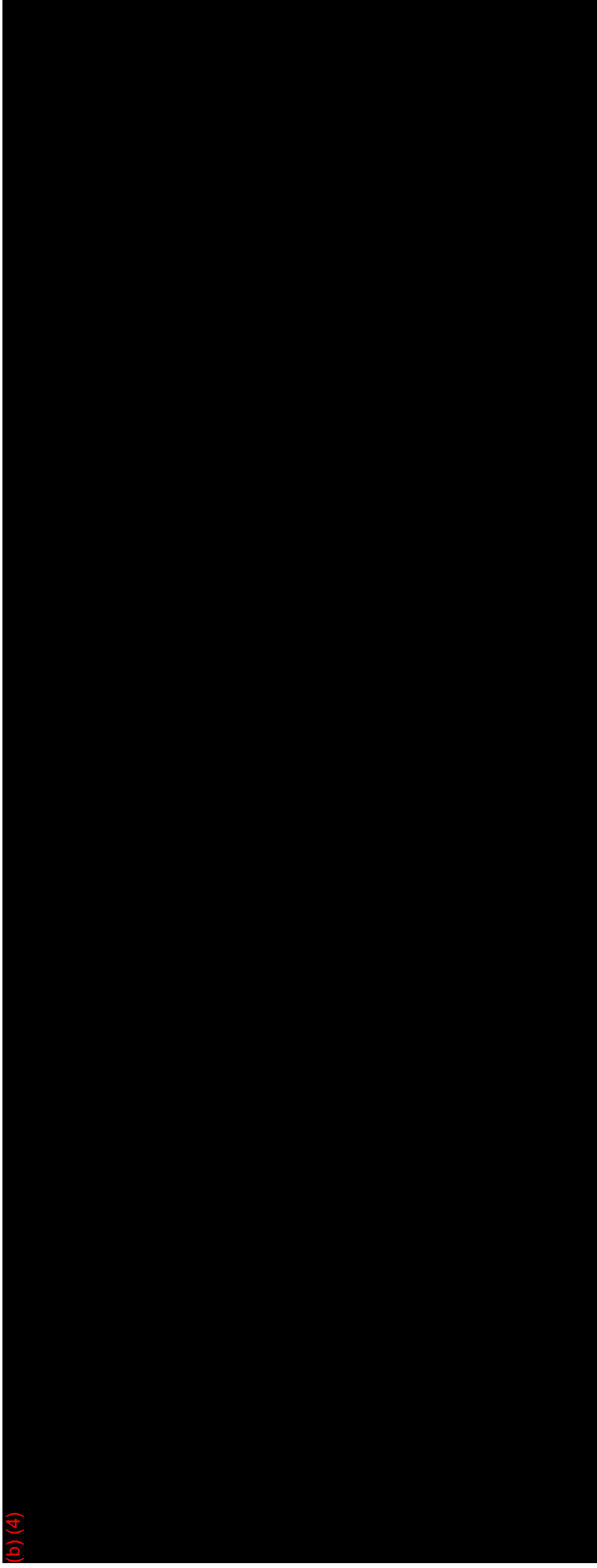
**M0005 Exhibit A - Total Yearly Budget Details**

(b) (4)



**M0005 Exhibit A - Total Yearly Budget Summary**

(b) (4)



## Summary Allocation

(b) (4)



(b) (4)



(b) (4)

(b) (4)

## ATTACHMENT 1: TASK DESCRIPTION DOCUMENT (SOW)

### Overall Objectives and Scope

Seasonal and pandemic influenza remains one of the most important public health threats despite current vaccine and therapeutic options. The Consortium is developing a broad portfolio of innovative and novel countermeasures against influenza and other emerging infectious diseases comprising small molecules, biologics and vaccines. The portfolio employs (b) (4) modes of action complementary to current Standard of Care treatments to develop single or combination therapies that have the potential to increase therapeutic benefit and preclude the rapid emergence of drug resistance. The (b) (4) aims to (b) (4) the influenza vaccine field by providing broad protection for both seasonal and pandemic influenza.

Specifically, this Agreement includes: an influenza (b) (4) that is now ready for (b) (4) (b) (4) a (b) (4) influenza A or B viruses; a (b) (4); and (b) (4)

In addition, Recipient may propose to augment the portfolio by replacing molecules listed in this SOW with backup molecules from their ongoing research programs. With support from the JOC, the Consortium may also consider in-licensing drug or vaccine candidates to supplement the Program's portfolio of emerging infectious disease medical countermeasures in the Field. Recipient may also add Consortium Members as may be appropriate or complimentary to the performance and goals of this Agreement.

(b) (4)



(b) (4)



(b) (4)

## 6 Project Management

Coordinating project management has been brought under WP 5.6 as per JOC memo 4 (initially in 1.6)

### 6.1 Joint Oversight Committee – check updated language from more recent MOD

The Joint Oversight Committee (JOC) is the larger decision-making body that provides guidance, direction and control to the projects to ensure execution of the projects according to the SOW. The JOC will discuss and approve any changes to the SOW. To that extent, the JOC will meet at critical decision points in the program, but no less than two times per year, preferably face to face or alternatively by WebEx or telephone conference. Ad hoc meetings will be organized when urgent matters arise. The JOC will consist of voting and non-voting members from BARDA and Janssen. Additional, non-voting members can be assigned or invited on an ad hoc basis. Decisions to reprioritize specific projects and resources as the need arises will be taken by consensus. In case such a decision cannot be reached in the JOC, the decision will be escalated to one BARDA and one Janssen senior management member identified at the start of the project.

### 6.2 PMO Steering Committee

The PMO (Program Management Organization) steering committee has dual responsibilities. One area of responsibility is the communication and coordination with BARDA regarding day to day management and execution of the project e.g. organizing meetings on a regular agreed basis. In addition, the PMO Steering Committee will coordinate all SOW activities and provide the technical and administrative infrastructure to ensure efficient planning, initiation, implementation, direction, management and completion of all tasks. This will be coordinated by the Project Manager Leader (PML). The Steering Committee will assess progress and where needed will work out strategic changes to be decided upon by the JOC. The Steering Committee consists of a group of dedicated and specialized Project Management experts, key personnel and additional specific expertise for the functions that are required for executing the specific work scope for each proposed asset area.

### 6.3 Asset Project Management

These WPs include the Program Management activities associated with each of the assets. Each asset will have an **Asset Project Management Leader (Asset PML)** who will oversee their specific **Project Management** requirements. This includes conducting frequent and regular **Project Management Team (PMT)** meetings to ensure the accurate developing and tracking of the budget, timeline and resource plan. The **Project Management team** of each asset will also include Technical Lead, Preclinical Leader, Clinical Leader, the CMC Leader, the Regulatory Project Management Leader and Finance representatives. Additional expertise required for executing asset-specific work

possibly including subcontractors may be added as part of the Project Management Team.

## BARDA/Janssen Research &amp; Development LLC - Influenza and Emerging Pathogens OTA

Contract Number: HHSO100201700018C

## Joint Oversight Committee – Decision Document

Date:	2 Dec 2019	
JOC Meeting Number:	8	
JOC Participants:	Janssen reps: (b) (6)	BARDA reps: (b) (6)
Assets Reviewed:	(b) (4)	
Decision Requested, Rationale and Budget Impact:	(b) (4)	

(b) (4)



(b) (4)



M0005 Exhibit E

**JOC Member Approvals:**

(b)(4) and (b)(6)

